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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/488,867	01/21/2000	Michael J. Imperiale	11203-002001	5039

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EXAMINER	
WHITEMAN, BRIAN A	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 12/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/488,867	IMPERIALE, MICHAEL J.	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *9/8/03*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,13,14,17-27,31-35 and 40-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *20-22,35* is/are allowed.

6)☒ Claim(s) *1-11,13,14,17-19,23-27,31-34 and 40-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Non-Final Rejection

Claims 1-11, 13, 14, 17-27, 31-35, and 40-42 are pending examination.

Applicant's traversal, the amendment to claims 2, 6, 10, 13, 22, 27, and 42 in paper no. filed on 9/8/03 is acknowledged and considered.

Upon further consideration, the indicated allowability of claims 1, 3-5, 18, 23-25, 31-34, 40, and 41 is withdrawn in view of the new 112 first paragraph and 112 second paragraph rejection.

Response to Arguments

Applicant's arguments, see paper no., filed on 9/8/03, with respect to objection have been fully considered and are persuasive. The objection of claims 6-8, 17, 22, and 27 has been withdrawn because of the amendment to the claims (see page 1).

Applicant's arguments, see paper no., filed on 9/8/03, with respect to 112 first paragraph rejection have been fully considered and are persuasive. The rejection of claims 9 and 42 has been withdrawn because of the amendment to the claim 42 (see pages 1 and 2).

Applicant's arguments, see paper no., filed on 9/8/03, with respect to 112 second paragraph rejection have been fully considered and are persuasive. The rejection of claims 2, 10, 11, 13, 14, 19, 26, and 27 has been withdrawn because of the amendment to the claims (see pages 2 and 3).

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (e.g., page 17, line 31). Applicant is required to delete any embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 13, 14, 26, and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

> Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in In re Wands, 858 F.2d 731, 8USPQ2d 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The specification provide sufficient and/or factual evidence for using an in vitro cell expressing an adenovirus 52/55 kDa trans-acting protein or a nucleotide sequence encoding an adenovirus 52/55 kDa trans-acting protein for producing the claimed vector system (pages 34-35). However, the specification lacks sufficient guidance using an isolated adenovirus 52/55 kDa trans-acting protein for producing the claimed vector system. The specification does not

teach how to get the protein into the cell. The specification does not teach when to administer the protein or how much of the protein to deliver to a cell to produce the replication defective adenovirus. The specification recites that, "how exactly the 52/55 kDa protein is involved in the genome encapsulation process is unknown (page 9)." If the protein is not already expressed in the cell, the specification does not teach how to get the protein into the cell and avoid degradation of the protein before the protein is required for packaging of the first adenovirus sequence. The art of record is absent for how to get the protein into the cell and when to administer the 52/55 kDa protein to produce the claimed adenovirus. Therefore, it would take one skilled in the art an undue amount of experimentation to practice the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 14, 15, 18, 19, 23, 24, 25, 26, 27, 31, 32, 33, 34, 40, 41, and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: using a cis-acting packaging sequence from the same adenovirus, e.g., using a first and second adenovirus cis-acting packaging sequence from adenovirus type 2. The specification teaches that the first adenovirus cis-acting packaging

sequence is from a different serotype than the second cis-acting packaging sequence, e.g., claims 4 and 5. However, the claims read on using the same serotype for both cis-acting packaging sequences.

Suggest adding a limitation to the claims to define that the first adenovirus cis-acting packaging sequence is from a different serotype than the second adenovirus cis-acting packaging sequence.

Claims 23, 24, and 25 recite the limitation "second adenovirus serotype- specific a nucleic acid sequence". There is insufficient antecedent basis for this limitation in the claim. Suggest replacing the limitation with -- second adenovirus serotype-specific sequence --.

Claims 31, 32, 33, and 34 recite the limitation "the first replication defective adenovirus sequence" in step (b) of both claims. There is insufficient antecedent basis for this limitation in the claim. Suggest replacing the limitation with -- the first adenovirus sequence --.

Claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 14, 15, 18, 19, 26, 27, 31, 32, 33, 34, 40, 41, and 42 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: trans-acting elements required to produce and package a replication defective adenoviral vector. The specification defines that the second adenovirus nucleic acid is considered a helper virus for producing the adenovirus, however the claims fail to define that the second nucleic acid is a helper virus.

With support from the specification suggest adding a limitation to the second adenovirus nucleic acid sequence that would embrace trans-acting elements used to produce the replication defective adenoviral vector.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 17, 19, and 42 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 9 and 10 of copending Application No. 10/135,895. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims from both application embrace a vector system for packaging a replication defective adenovirus using a nucleic acid sequence encoding an adenovirus 52/55 kDa trans-acting protein.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Claims 20-22 and 35 are in condition for allowance because they are free of the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, acting SPE - Art Unit 1635, can be reached at (703) 306-3217.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman
Patent Examiner, Group 1635

Scott D. Priebe

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER